## **EXHIBIT A**

Wong, Charlene A. (CDC/IOD) From: Sent: Wed, 23 Oct 2024 21:58:32 +0000

Fristedt, Andi Lipstein (CDC/IOD); Wolff, Kate L. (CDC/IOD/OCS); Petersen, Ruth To:

(CDC/NCCDPHP/DNPAO); Gunn, Janelle P. (CDC/NCCDPHP/DNPAO); Hamner, Heather

(CDC/NCCDPHP/DNPAO); Schwarcz, Cristi L. (CDC/IOD/CDCWO); Loverde, Maria (CDC/IOD/CDCWO) Reczek, Jeffrey (CDC/IOD/CDCWO); Houry, Debra E. (CDC/IOD); Hacker, Karen

(CDC/NCCDPHP/OD); Mahmood, Aisha (CDC/IOD/OCS) RE: Update: NEC/premie formula Subject:

Attachments: Roundtable on Strategies to Improve Access to Human Milk in NICUs Run of

Show and Participants DRAFT.docx

## Hi all,

Few updates from a brief S1 prep meeting today for a partner roundtable tomorrow:

- 1. Partner roundtable: S1 hosting tomorrow, see attached run of show. My comments will include reviewing our data on donor milk and mom's own milk use in NICUs + summarizing what we've heard are strategies needed to increase human milk access in NICUs (i.e., closing the gap on NICUs without any donor milk use, increasing breast milk donations and increasing practices to support mom's own milk in NICUs).
- 2. Administrative Option: No major updates. HHS continues to be in conversation with manufacturers.
- 3. Legislative Options: Continuing to work with manufacturers who have different points of view on options (e.g., compensation program) that will solve on the issue and are passable. ASL also working with sponsors of donor milk act to be sure the bill has the funding it needs.

Heather and I will share key updates from the roundtable tomorrow.

Thanks!

~Charlene

From: Wong, Charlene A. (CDC/IOD) Sent: Friday, October 11, 2024 12:35 PM

To: Fristedt, Andi Lipstein (CDC/IOD) <lsa5@cdc.gov>; 'Wolff, Kate L. (CDC/OD/OCS)' <uqq9@cdc.gov>; Petersen, Ruth (CDC/NCCDPHP/DNPAO) <rip0@cdc.gov>; Gunn, Janelle P. (CDC/NCCDPHP/DNPAO) <br/><br/>/bfy2@cdc.gov>; Hamner, Heather (CDC/NCCDPHP/DNPAO) <br/>/hfc2@cdc.gov>; Schwarcz, Cristi L. (CDC/IOD/CDCWO) <zcj1@cdc.gov>; Loverde, Maria (CDC/IOD/CDCWO) <nzk0@cdc.gov> Cc: Reczek, Jeffrey (CDC/IOD/CDCWO) <msq5@cdc.gov>; Houry, Debra E. (CDC/IOD) <vjz7@cdc.gov>;

Hacker, Karen (CDC/NCCDPHP/OD) <pju3@cdc.gov>; Mahmood, Aisha (CDC/IOD/OCS)

<qmo2@cdc.gov>

Subject: RE: Update: NEC/premie formula

Hi team,

End of week brief update:

- Legislative strategy: ASL touching base with Abbott and will set-up conversation with Reckitt-Mead Johnson to understand their leg outreach and strategy. IEA will help build coalition of messengers (e.g., pediatricians, patient groups) with message focused on importance of assuring babies are fed.
- Roundtable on access to human milk in NICU: In WH call today, Steve highlighted change in framing from "donor milk" to "human milk" to ensure inclusion of increasing access to mom's own milk. HHS incorporated our input on roundtable goals/participants. No update on anticipated timing. Still awaiting feedback from AAP on collaborative project on human milk (
   AAP Project Scope HumanMilk draft 10.01.24.docx).
- 3. Administrative/contracting option: OGC continuing to pressure test here. FDA with same concerns about labeling implications. Andi/Kate can provide more details in our touch bases.
- HHS consensus statement: HHS has heard positive feedback on this statement on human milk, formula and NEC.
- 5. **Data on human milk in NICUs**: See the attached new, expedited publication with more details on human milk use in NICUs than what we posted earlier on our website.
- 6. **PQCs**: DRH summarized work that PQCs have done to increase human milk in NICUs in the attached word doc. Looking into PQC-created resources to potentially re-lift or update.

Welcome additions, questions. Thx!

Best, Charlene

From: Wong, Charlene A. (CDC/IOD) Sent: Monday, October 7, 2024 5:15 PM

To: Fristedt, Andi Lipstein (CDC/IOD) <a href="mailto:lipstein">lsa5@cdc.gov</a>; Petersen, Ruth (CDC/NCCDPHP/DNPAO) <a href="mailto:lipstein">lipo@cdc.gov</a>; Gunn, Janelle P. (CDC/NCCDPHP/DNPAO) <a href="mailto:lipstein">bfy2@cdc.gov</a>; Hamner, Heather (CDC/NCCDPHP/DNPAO) <a href="mailto:lipstein">hfc2@cdc.gov</a>; Schwarcz, Cristi L. (CDC/IOD/CDCWO) <a href="mailto:lipstein">zcj1@cdc.gov</a>; Loverde, Maria (CDC/IOD/CDCWO) <a href="mailto:lipstein">nzko@cdc.gov</a>; Schwarcz, Cristi L. (CDC/IOD/CDCWO) <a href="mailto:lipstein">nzko@cdc.gov</a>; Loverde, Maria (CDC/IOD/CDCWO) <a href="mailto:lipstein">nzko@cdc.gov</a>; Schwarcz, Cristi L. (CDC/IOD/CDCWO) <a href="mailto:lipstein">nzko@cdc.gov</a>; Loverde, Maria (CDC/IOD/CDCWO) <a href="mailto:lipstein">nz

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Subject: Update: NEC/premie formula

Hi team,

Quick read out of the S1 briefing on NEC/premie formula. Focused on the 2 legislative options: S1's steer at the end was to go all in on increasing access to donor milk. He said something to the effect of use as much authority and resourcing as we can get to boost up donor milk access.

1. Donor milk legislation

- a. S1 asked questions about if donor milk fully solves liability issue answer is no (e.g., babies who get only human milk, mom's own or donor milk, can still get NEC). However, reduces risk and reiterated multiple benefits of human milk for VLBW infants. Importance of increasing access to mom's own milk and questions of cost/coverage for donor milk also came up on the call.
- b. S1 supportive of a stakeholder roundtable on increasing access to human milk Steve suggested could happen in next 1-2 wks. We've provided feedback on participant list.
- c. CDC included suggestions on the legislative draft for funding needs for a donor milk campaign (increase from \$1M to \$2M), increasing access to mom's own milk (\$1M – DNPAO team, increased this after talking with Jeff)
- 2. Compensation liability legislation
  - a. Multiple outstanding policy questions. S1 steer was to keep this focused/narrow.

Multiple barriers identified in a brief discussion on indemnification option. Andi – welcome any of your additions from the briefing.

## Other related tidbits:

- Expect AAP edits to the donor milk project proposal per the HHS/AAP meeting last week AAP Project Scope HumanMilk draft 10.01.24.docx. Also expect follow up calls with at least AHA soon.
- Cristi and Maria have added you to the weekly meeting with DNPAO on this issue to keep us all coordinated
- PQCs ACOG noted that there have been at least 2 PQCs that have taken increasing access to donor milk as a project. DRH is pulling info on these PQC efforts
- Thanks to DNPAO for expediting posting of our data on NICU use of donor milk, now posted here: mPINC 2022 National Results Report | Breastfeeding | CDC

## ~Charlene

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